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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,161	03/01/2007	Fabrice Agou	288459U/SOX PCT	6621
22850	7590	06/23/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
MONSHIPOURI, MARYAM				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
06/23/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

**Application No.**

10/573,161

**Applicant(s)**

AGOU ET AL.

**Examiner**

Maryam Monshipouri

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-6 and 8-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 3-6, 8-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

Applicant's response to restriction requirement filed 3/5/2009 is acknowledged. Applicant elected Group I, claims 1-14, and invention (a) human NEMO CC2 with traverse. Claims 2 and 7 are canceled. Claims 1, 3-6, 8-57 are still pending.

In traversal of previous restriction requirement applicant argues that no burden of undue searching and examination would be imposed if all Groups I(a)-VI (see below) and Groups (a)-(f) would be examined together. In the present case each Group involves NF-kB inhibitors, DNA encoding such inhibitors and methods of use of said inhibitors. Moreover, species (a)-(f) represent sequences which display significant structural identity (as shown by the attached sequence alignment data) and thus they are related in structure and function, irrespective of whether they are derived from human or murine source.

These arguments were fully considered but were found unpersuasive. **Firstly** applicant refers to inventions of Groups (a)-(f) as species while the examiner explicitly indicated that said Groups are patentably distinct inventions and not species. **Secondly**, the examiner is unclear as to what applicant means by "inhibitors of NF-kB". Instant claims mention "inhibitors of NF-kB signaling pathway" and their methods of use and not NF-kB or inhibitors thereof alone. Applicant is well aware that "inhibitors of NF-kB pathway" are directed to upstream and downstream modulators of NF-KB as well as said protein itself . Therefore, applicant can appreciate that, inhibitors of such pathway depending on their target protein, can incorporate numerous products with entirely different structures and modes of action, sharing no common technical features, whose rejoinder no doubt, imposes an undue burden of searching on the examiner.

**Thirdly**, the examiner acknowledges that human and murine NEMO may display significant structural homology but said structural similarity (homology) does not justify rejoinder of Groups (a)-(f) because instant claims are not restricted to said NEMO protein inhibitors (or their method of use) but rather, to inhibitors (or method of use thereof) of proteins that merely need to incorporate (comprise) a small region (such as CC2 domain, LZ domain etc.) of either of said human or murine proteins, which may have nothing (or very little) to do with NEMO proteins or inhibitors thereof. Therefore, the examiner maintains that rejoinder of Groups (a)-(f) , in contrast to applicant's view, does impose an undue burden of searching and examination on the Office.

In conclusion, in view of the response provided above in addition to explanations provided previously, restriction is maintained according to previous office action and is hereby made **Final**.

The examiner regrets not having the preliminary amendment of 10/29/07 considered (as mentioned by applicant) before drafting the previous office action. In view of said inadvertent error and in view of applicant's amendments to the instant claims a supplemental lack of unity letter deemed necessary. The previous Grouping of claims I-VII is substituted with the following grouping:

**Group I(a)**, claims 1, 3-6, 8 and 46-53, drawn to isolated DNA encoding an intact non-fusion Nf-kB inhibitor, vectors and host cells comprising said products and their expression products.

**Group I(b)** , claims 9-14, 15, 54-57, drawn to fusion polypeptides that inhibit NFkB pathway and a method of use of said fusion polypeptides of Group I(b).

**Group II**, claim 16, drawn to a method of disrupting NEMO oligomerization utilizing said fusion polypeptides of Group I(b).

**Group III**, claims 17-22, drawn to a method of use of non-fusion polypeptides of Group I(a), for treating a disorder regulated by NF-kB signaling pathway.

**Group IV**, claims 23-27, a method for regulating cell proliferation or apoptosis, comprising administering fusion polypeptides of Group I(b).

**Group V**, claims 28-32, a method for regulating B and T lymphocytes in stimulation of antigenic stimulation comprising administering said fusion polypeptides of Group I(b).

**Group VI**, claims 33-45, drawn to a method of identifying modulators of NEMO oligomerization utilizing fusion polypeptides of Group I(b).

In addition to inventions listed as Groups I(a)-VI each invention is additionally and independently directed to the following products of unrelated chemical structure and function, which are patentably distinct each from the ether:

- (a) human NEMO CC2 motif derivatives.
- (b) murine NEMO CC2 motif derivatives
- (c ) human NEMO LZ domain derivatives.
- (d ) murine NEMO LZ domain derivatives .
- (e) human NEMO NLM motif derivatives.
- (f) murine NEMO NLM motif derivatives.

When electing any of the inventions of Groups I-VII applicant is advised to simultaneously elect an invention from Groups (a)-(f) as well. **This not a species election.**

The inventions listed as Groups I(a) -VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical features of Group I (a) and I9b) are intact NF-kB inhibitors, and fused NF-kB inhibitors which share no common technical feature. Groups I(a) and IV share a special technical feature, namely inhibitors of intact NF-kB but said inventions are not required to be rejoined under PCT Rule 13.1 because Group I(a) invention already has a method of use of polypeptide inhibitors.

Similarly, the inventions of Groups I(b) -VI share a common technical feature, namely, a method of use of polypeptide inhibitors of fusion polypeptides but said inventions are not required to be rejoined under PCT Rule 13.1 because Group I(b) invention already has a method of use of fusion polypeptide inhibitors.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention From Groups I(a)-(b) to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. **Applicant is requested to identify all SEQ ID NO's that correspond to the elected invention, or preferably provide a table as to which SEQ ID NO's correspond to which of the Groups (a)-(f) for clarity of record.**

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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